Chapter 2.3.13 – Bovine Spongiform Encephalopathy

General comment:
Given additional technical information, the United States kindly requests that the AHC Commission consider updating the Code Chapter on BSE as follows:

Articles 2.3.13.8 and 2.3.13.21.

Current OIE text:

Article 2.3.13.8.

Regardless of the BSE status of the *exporting country*, *Veterinary Administrations* should authorise without restriction the import or transit through their territory of the following *commodities*:

1) milk and milk products;

2) semen and [embryos] *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;

3) protein-free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;

4) dicalcium phosphate (with no trace of protein or fat);

5) hides and skins;

6) gelatin and collagen prepared exclusively from hides and skins.

Article 2.3.13.21.

Veterinary Administrations of *importing countries* should require:

for tallow (other than protein-free tallow as defined in Article 2.3.13.8.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biological, or medical devices

the presentation of an *international veterinary certificate* attesting that it originates from:

1) a BSE free or provisionally free country or zone; or

2) a country or zone with a minimal BSE risk, and

   [a) if prepared by fat melting,] it originates from cattle which have been subjected to an ante-mortem inspection for BSE with favourable results and has not been prepared using the tissues listed in point [2)b)] 3 of Article 2.3.13.19.;

   [b) if prepared by rendering, (under study);] or

3) a country or zone with a moderate BSE risk; and

[a) if prepared by fat melting,] it originates from cattle which have been subjected to an ante-mortem inspection for BSE with favourable results and has not been prepared using the tissues listed in point 2[)a)] of Article 2.3.13.19.

[b) if prepared by defatting of bones:

i) skulls and vertebral columns from cattle over 6 months of age have been excluded; or

ii) it has been processed using a method that reduces the infectivity by at least 5 $\log_{10}$ LD_{50}/g (processes under study);

c) if prepared by rendering, (under study).]

Suggested text:

`Article 2.3.13.8.`

Regardless of the BSE status of the *exporting country*, *Veterinary Administrations* should authorise without restriction the import or transit through their territory of the following *commodities*:

1) milk and milk products;

2) semen and [embryos] *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;

~~[3) protein free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;]~~

4) dicalcium phosphate (with no trace of protein or fat);

5) hides and skins;

6) gelatin and collagen prepared exclusively from hides and skins.

`Article 2.3.13.21.`

Veterinary Administrations of *importing countries* should require:

for **all** tallow ~~[(other than protein free tallow as defined in Article 2.3.13.8.)]~~ intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biological, or medical devices

the presentation of an *international veterinary certificate* attesting that it originates from:

1) a BSE free or provisionally free country or zone; or

2) a country or zone with a minimal BSE risk, and

[a] if prepared by fat melting,] it originates from cattle which have been subjected to an ante-mortem inspection for BSE with favourable results and has not been prepared using the tissues listed in point [2)b)] 3 of Article 2.3.13.19.;

[b] if prepared by rendering, (under study);] or

3) a country or zone with a moderate BSE risk; and

[a] if prepared by fat melting,] it originates from cattle which have been subjected to an ante-mortem inspection for BSE with favourable results and has not been prepared using the tissues listed in point 2[)a)] of Article 2.3.13.19.

[b] if prepared by defatting of bones:

i) skulls and vertebral columns from cattle over 6 months of age have been excluded; or

ii) it has been processed using a method that reduces the infectivity by at least 5 $\log_{10}$ LD_{50}/g (processes under study);

c) if prepared by rendering, (under study).]

Rationale: Article 2.13.8 (and also referenced in Article 2.13.21) allows certain commodities to be traded without restriction regardless of the BSE status of a country/zone. One of these commodities is "protein-free" tallow. However, this recommendation allows for such tallow to have a "maximum level of impurities of 0.15% by weight". Given the circumstantial evidence which indicates possible transmission of BSE via milk-replacer with added fat or contaminated tallow, the United States asks the AHC Commission to re-evaluate the safety of this impurity level.

The EU SSC opinion on the safety of tallow also calls into question tallow as a potential vehicle to spread BSE. If there is likelihood that "protein free" tallow may pose any risk, it is prudent to put some safeguards in place as it is often an additive to feedstuffs for the most susceptible species (calves). The long incubation period and insidiousness associated with BSE warrants prevention rather than reaction.

Articles 2.3.23.15, 2.3.13.16, and 2.3.13.19

Current OIE text:

Article 2.3.13.15.

When importing from a country or zone with a minimal BSE risk, *Veterinary Administrations* should require:

for *fresh meat* (bone-in or deboned) and *meat products* from cattle

the presentation of an *international veterinary certificate* attesting that:

1) the country or zone complies with the conditions in Article 2.3.13.5. to be considered as presenting a minimal BSE risk;

2) ante-mortem inspection is carried out on all cattle from which the meat or *meat products* destined for export originate;

3) cattle from which the meat or *meat products* destined for export originate were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process (laceration, after stunning, of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity);

4) the *fresh meat* and *meat products* destined for export do not contain brain, eyes, spinal cord or mechanically separated meat from skull and vertebral column from cattle over 30 months of age, all of which have been removed in a hygienic manner.

Article 2.3.13.16.

When importing from a country or zone with a moderate BSE risk, *Veterinary Administrations* should require:

for *fresh meat* (bone-in or deboned) and *meat products* from cattle

the presentation of an *international veterinary certificate* attesting that:

1) the country or zone complies with the conditions in Article 2.3.13.6. to be considered as presenting a moderate BSE risk;

2) the feeding of ruminants with *meat-and-bone meal* and greaves derived from ruminants has been banned and the ban has been effectively enforced;

3) ante-mortem inspection is carried out on all bovines;

4) cattle from which the meat or *meat products* destined for export originate were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process;

5) the *fresh meat* and *meat products* destined for export do not contain brain, eyes, spinal cord, distal ileum or mechanically separated meat from skull and vertebral column from cattle over 6 months of age, all of which have been removed in a hygienic manner.

Article 2.3.13.19.

1) The following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biological, or medical devices: brains, eyes, spinal cord, tonsils, thymus, spleen, intestines, dorsal root ganglia, trigeminal ganglia, skull and vertebral column, and protein products derived therefrom, from cattle over 6 months of age originating from countries with a high BSE risk. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

2) The following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biological, or medical devices:

a) brains, eyes, spinal cord, distal ileum, skull, vertebral column and protein products derived therefrom, from cattle, originating from a country or zone with a moderate BSE risk, that were at the time of slaughter aged over 6 months;

b) brains, eyes and spinal cord, skull, vertebral column and protein products derived therefrom, from cattle, originating from a country or zone with a minimal BSE risk has been reported, that were at the time of slaughter aged over 30 months.

Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using the commodities listed in points a) and b) above should also not be traded.

Suggested text:

Article 2.3.13.15.

When importing from a country or zone with a minimal BSE risk, *Veterinary Administrations* should require:

for *fresh meat* (bone-in or deboned) and *meat products* from cattle

the presentation of an *international veterinary certificate* attesting that:

1) the country or zone complies with the conditions in Article 2.3.13.5. to be considered as presenting a minimal BSE risk;

2) ante-mortem inspection is carried out on all cattle from which the meat or *meat products* destined for export originate;

3) cattle from which the meat or *meat products* destined for export originate were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process (laceration, after stunning, of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity);

4) the *fresh meat* and *meat products* destined for export do not contain brain, eyes, spinal cord or mechanically separated meat from skull and vertebral column from cattle **of any age** [**over 30 months of age]**, all of which have been removed in a hygienic manner.

Article 2.3.13.16.

When importing from a country or zone with a moderate BSE risk, *Veterinary Administrations* should require:

for *fresh meat* (bone-in or deboned) and *meat products* from cattle

the presentation of an *international veterinary certificate* attesting that:

1) the country or zone complies with the conditions in Article 2.3.13.6. to be considered as presenting a moderate BSE risk;

2) the feeding of ruminants with *meat-and-bone meal* and greaves derived from ruminants has been banned and the ban has been effectively enforced;

3) ante-mortem inspection is carried out on all bovines;

4) cattle from which the meat or *meat products* destined for export originate were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process;

5) the *fresh meat* and *meat products* destined for export do not contain brain, eyes, spinal cord, distal ileum or mechanically separated meat from skull and vertebral column from cattle **of any age [over 6 months of age]**, all of which have been removed in a hygienic manner.

Article 2.3.13.19 points 1) and 2a) and b)

Article 2.3.13.19.

1) The following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biological, or medical devices: brains, eyes, spinal cord, tonsils, thymus, spleen, intestines, dorsal root ganglia, trigeminal ganglia, skull and vertebral column, and protein products derived therefrom, from cattle [over 6 months] of any age originating from countries with a high, **moderate or minimal** BSE risk. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

~~[2) The following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biological, or medical devices:~~

~~a) brains, eyes, spinal cord, distal ileum, skull, vertebral column and protein products derived therefrom, from cattle, originating from a country or zone with a moderate BSE risk, that were at the time of slaughter aged over 6 months;~~

~~b) brains, eyes and spinal cord, skull, vertebral column and protein products derived therefrom, from cattle, originating from a country or zone with a minimal BSE risk has been reported, that were at the time of slaughter aged over 30 months.~~

~~Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using the commodities listed in points a) and b) above should also not be traded.]~~

Rationale: These sections as currently written allow for certain very high risk commodities (e.g. brain and spinal cord) from high risk BSE countries (point 1) or minimal and moderate risk BSE countries to be traded for the manufacture of food, feed, cosmetics and pharmaceuticals. The United States strongly recommends that such high risk commodities not be traded from any age animal from any BSE risk country. A couple of sound reasons exist for this recommendation:

1. The risk categories are not based on any hard science. Any country with a large cattle population may have a significant number of BSE cases and still be placed in a minimal or moderate risk category. For example, given the size of its cattle population, the United States is permitted to have up to 39 cases of BSE per year for 4 consecutive years and still be considered a country with minimal risk for BSE. For moderate risk countries, and again using the cattle population in the United States for illustration purposes, up to 4000 cases per year would be permitted under a passive surveillance system and up to 8000 cases under an active surveillance system.
2. As diagnostic techniques have improved, tissues which were previously thought to have no infectivity at all, have been shown to be infective (e.g. blood, tonsil). This may also hold true for the age of the animal where infectivity is first detected in certain tissues. The age limit of 6 months gives no room for biological variation. In the BSE pathogenesis study, infectivity was detected in the distal ileum at 6 months post-inoculation in both the mouse and calf bioassay systems. This would indicate that if calves were infected shortly after birth, there would be infectivity present in the distal ileum at 6 months of age. This recommendation would be consistent with Articles 2.3.13.15, 2.3.13.16 and 2.3.13.17 where there is no lower age limit on the process of stunning or pithing. These procedures are prohibited due to the potential for disseminating CNS tissue to other areas of the body or contaminating other tissues. If these procedures (stunning and pithing) are a risk at any age, then procedures (i.e. mechanically separating meat) which likely result in even more CNS contamination of other tissues, should also be prohibited.

Appendix 3.8.4 – Bovine Spongiform Encephalopathy

SURVEILLANCE AND MONITORING SYSTEMS FOR BOVINE SPONGIFORM ENCEPHALOPATHY

OIE proposed text:

Surveillance programmes developed before the advent of rapid diagnostic tests focused on the sub-population containing cattle displaying clinical signs compatible with BSE as described in Article 3.8.4.2. While surveillance should focus on this sub-population, investigation of other sub-populations using the new diagnostic techniques may provide a more accurate picture of the BSE situation in the country or zone. A surveillance strategy may therefore need to combine several strategies. Recommended strategies for surveying the various sub-populations are described below.

Suggested text (changes in bold):

Surveillance programmes **~~[developed before the advent of rapid diagnostic tests]~~** should **be** focused on the sub-population containing cattle displaying clinical signs compatible with BSE as described in Article 3.8.4.2. While surveillance should focus on this sub-population, investigation of other sub-populations **~~[using the new diagnostic techniques]~~** may provide a more accurate picture of the BSE situation in the country or zone **particularly if determined to have been exposed to BSE risk factors**. **Depending on the BSE risk associated within that country or zone, a** [**A**] surveillance strategy may [**therefore**] need to combine several strategies, Recommended strategies for surveying the various sub-populations are described below.

Rationale:

While the United States supports the use of different testing techniques for BSE, prescribing the specific use of certain diagnostic tests is inappropriate. Furthermore, certain tests, such as the rapid tests, may not give an accurate picture of the BSE situation in a country or zone. It is well known that certain rapid tests such as the Enfer ® and Biorad ® tests have recorded false positive BSE results. For BSE free countries or zones, the use of rapid BSE tests that give false positive results will cause loss of consumer confidence in beef and beef products. As is true for any control, eradication or surveillance program, a combination of tests is the best approach. For BSE free countries or zones, the use of histopathology, immunohistochemistry and the Prionics 'check' immunoblot test would provide a definitive diagnosis of a BSE suspect case. It should be noted that testing by immunohistochemistry has been found to be as sensitive as other approved diagnostic techniques and more specific.

OIE proposed text:

Available data suggest the possibility that a gradient might be established to describe the relative value of surveillance applied to each sub-population. All countries should sample sub-pops identified in Articles 3.8.4.2. and 3.8.4.3. In countries where surveillance of cattle identified in Article 3.8.4.2. is unable to generate the numbers recommended in Table 1, surveillance should be enhanced by testing larger numbers of cattle identified in Article 3.8.4.3. Any shortfall in the first two sub-pops should be addressed by the sampling of normal cattle over 30 months of age at slaughter. Exclusive dependence on random sampling from normal cattle is not recommended, unless the number of samples examined annually is statistically sufficient to detect a disease prevalence of 1 in 1,000,000.

Suggested text:

Available data suggest the possibility that a gradient might be established to describe the relative value of surveillance applied to each sub-population. All countries should sample **the sub-population [sub-pops]** identified in Article**[s]** 3.8.4.2. **[and 3.8.4.3]**. In countries where surveillance of cattle identified in Article 3.8.4.2. is unable to generate the numbers recommended in Table 1, surveillance should be enhanced by testing larger numbers of cattle identified in Article 3.8.4.3. Any shortfall in the first two sub-pops should be addressed by the sampling of normal cattle over 30 months of age at slaughter. Exclusive dependence on random sampling from normal cattle is not recommended, unless the number of samples examined annually is statistically sufficient to detect a disease prevalence of 1 in 1,000,000.

Rationale:

BSE surveillance in free countries or zones should be directed to those the sub-populations of highest risk – where the disease is most likely to be found. Data from surveillance programs within European countries with BSE shows that clinical suspect cattle are by far the most likely sub-population that should be targeted in active surveillance programs. The best epidemiological surveillance data for BSE prevalence is from cattle showing signs consistent with BSE. It is only in situations where countries cannot test the minimum number of annual investigations of cattle showing clinical signs consistent with BSE, (as per table 1 in the appendix) that surveillance from fallen or emergency slaughter cattle should be sampled at much greater numbers to achieve the same confidence.